Bard Medical Division
C.R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

BARD | MEDICAL

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Bard RiteCath Intermittent Catheter 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:
BARD Medical Division
C. R. BARD, Inc.
8195 Industrial Blvd.
Covington, GA 30014
Establishment Registration Number: 1018233

Contact:
Michele Davis, RAC
Regulatory Affairs Project Manager
Bard Medical Division
Tel: 770-784-6274
Fax: 770-385-4706

Date:
April 2, 2014

Subject Device:
Trade Name: Bard® RiteCath™ Intermittent Urinary Catheter
Common Name: Urological Catheter
Classification Name: Urological catheter and accessories
Regulation: 21 CFR 876.5130
Classification: II
Primary Product Code: EZD
Secondary Product Codes: EZC

Legally marketed device to which substantial equivalence is claimed:

- Coloplast A/S Self Cath Catheter, K100878

Device Description

The Bard RiteCath Intermittent Urinary Catheter is a biocompatible, polyvinyl chloride (PVC) catheter used to drain urine from the bladder. The catheter consists of a funnel, shaft with two staggered eyelets and a tip. The tip is available in a straight or coude configuration. The tip of the catheter passes through the urethra into the bladder to allow urine to drain into the eyelets and then through the catheter shaft, exiting through the funnel. The catheter will be offered in multiple French sizes (8 – 18 Fr.), lengths (6" and 16") and two tip designs (straight and coude). The product is ethylene oxide sterilized (per ANSI/AAMI/ISO 11135-1:2007, *Sterilization of health care products – ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilized process for medical devices*). The catheter is for single use.

Intended Use
The Bard RiteCath Intermittent Urinary Catheter is intended for use by male and female patients for draining urine from the bladder.

Technological Characteristics
The Bard RiteCath Intermittent Urinary Catheter has the same technological characteristics as the predicate device. The subject and predicate device are made from the same catheter material, polyvinyl chloride (PVC) and have the same catheter design consisting of color-coded funnel, shaft, staggered eyelets, and straight or coude tip. The subject and predicate device are available in multiple French sizes and lengths.

Performance Data
Nonclinical functional performance testing was performed per BS EN 1616: 1997 + A1:1999, *Sterile urethral catheters for single use*. Nonclinical biocompatibility testing was conducted in accordance with ISO 10993-1:2009, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and FDA Bluebook Memorandum G95-1, Use of International Standard ISO 10993 "Biological Evaluation of Medical Devices Part 1: Evaluation of Testing."

Substantial Equivalence
The Bard RiteCath Intermittent Urinary Catheter has the same design features and is indicated for the same use as the predicate device, Coloplast Self Cath Catheter, K100878. The subject device is substantially equivalent to the legally, marketed predicate device and nonclinical test data demonstrates that the subject device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 4, 2014

C. R. Bard, Inc.
Michele Davis, RAC
Regulatory Affairs Project Manager
8195 Industrial Blvd.
Covington, GA 30014

Re: K133470
Trade/Device Name: Bard RiteCath Intermittent Urinary Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD, EZC
Dated: March 4, 2013
Received: March 6, 2014

Dear Michele Davis,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number: K133470

Device Name: Bard RiteCath Intermittent Urinary Catheter

INDICATIONS FOR USE:
The Bard RiteCath Intermittent Urinary Catheter is intended for use by male and female patients for draining urine from the bladder.

Prescription Use ☒ *(Part 21 CFR 801 Subpart D)* and/or **Over-the-Counter Use** ☐ *(21 CFR 807 Subpart C)*

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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